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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,478	06/20/2001	John A. Salon	57453-A-PCT-US/JPW/AJW	5447

7590 08/08/2002

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,478	SALON ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,32-34,41,43,47,83,96 and 97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11, 32-34, 41, 43, 47, 83, 96 and 97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-11, 32-34, 41, 43, 47, 83, 96 and 97 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 97, drawn to nucleic acid encoding human naturally occurring and mutant MCH1 receptors and method of making protein recombinantly, classified in class 536, subclass 23.5 and class 435, subclass 69.1.

II. Claim 11, drawn to MCH1 protein, classified in class 530, subclass 350.

III. Claims 32 and 34, drawn to antibody to MCH1 protein, classified in class 530, subclass 388.22, for example.

IV. Claim 33, drawn to an agent capable of competitively inhibiting the binding of antibody to MCH1 receptor, class and subclass undeterminable.

V. Claim 41, drawn to a transgenic nonhuman mammal expressing DNA encoding a human MCH1 receptor, classified in class 800, subclass 3.

VI. Claim 43, drawn to a transgenic nonhuman mammal expressing antisense DNA complementary to the DNA encoding a human MCH1 receptor, classified in class 800, subclass 3.

VII. Claims 47 and 83, drawn to a process for identifying a chemical compound which specifically binds to a mammalian MCH1 receptor or to a method of detecting MCH1 receptor on the surface of a cell, classified in class 435, subclass 7.1.

VIII. Claim 96, drawn to a method of purifying MCH1 receptor protein, classified in class 435, subclass 70.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and each of inventions II, V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acids can be used in the method of making the proteins of invention II or the transgenic non human mammals of inventions V and VI, but the nucleic acids can be used in a method of hybridization, which is a materially different process, and the proteins can be recovered from natural sources.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in the method of identifying a compound that binds to MCH1 receptor by using cells transformed with the encoding nucleic acids, but the nucleic acids can also be used in a method of hybridization, which is a materially different method.

The proteins of invention II are related to the antibodies of invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and

because the protein can be used in another and materially different process from the use for production of antibodies, such as in a method of therapy.

Inventions I and III are related as a process of making and a process of using a common product. The polynucleotides of invention I encode the polypeptide, which is the cognate antigen necessary for production of the antibody of invention III which is used in the method of detecting the MCH1 receptor of invention VII, but the nucleotides may also be used as probes in a method of hybridization, which are materially different methods. The processes are patentably distinct because of different starting and ending points, method steps and goals.

Inventions II and VII are related as product and process of use. In the instant case the protein can be used in the method of identifying a compound that binds to MCH1 receptor, but the protein can also be used in a method of generating antibodies, which is a materially different method.

Inventions VIII and II are related as process of making and product made. In the instant case the protein of invention II can be made by purifying it from cells that endogenously express the protein, but cells can also be used to make a different protein, and the protein can also be made recombinantly.

Inventions III and IV are related in that the unidentified agent can competitively inhibit the binding of the antibody to MCH1 receptor, but the antibody and agent are structurally and functionally distinct compounds.

Invention III is related to each of inventions VII and VIII as product and process of use. In the instant case the antibody of invention III can be used in a method of detecting the MCH1

protein of invention VII or in the method of purifying the protein of invention VIII, which are materially different methods having different starting materials, method steps and goals.

Invention I and each of inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids are unrelated to the unidentified compound that blocks the antibody from binding MCH1 receptor and are not necessary for the production of MCH1 receptor from cells naturally expressing the protein.

Inventions II and IV are unrelated. In the instant case the proteins are unrelated to the unidentified agent that blocks the antibody from binding MCH1 receptor.

Inventions V and VI are unrelated to inventions II-IV, VII and VIII because the transgenic animals are not used or defined in the methods or are structurally and functionally different from the products.

Inventions V and VI are unrelated because invention V is a transgenic animal that expresses DNA encoding a human MCH1 receptor and invention VI is a transgenic animal that expresses an antisense DNA complementary to the DNA encoding MCH1 receptor, so that in the animal of invention V MCH1 is expressed and in the animal of invention VI expression of MCH1 is reduced, so that the animals are made from different nucleic acid constructs and have different functions and goals.

Invention IV is unrelated to each of inventions VII and VIII because the unidentified agent is not used or defined in the methods.

Inventions VII and VIII are unrelated to each other, because they are methods that require different starting materials, and have different method steps and goals, and are distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and the need for non-coextensive literature search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

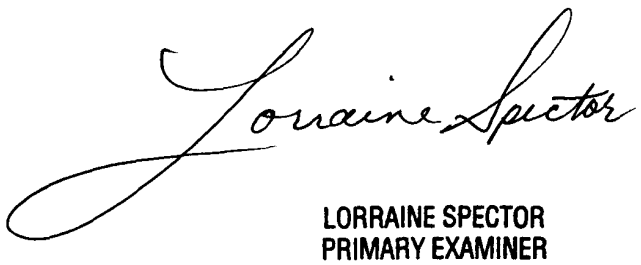
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR
PRIMARY EXAMINER